

REMARKS/ARGUMENT

Claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41-44, 51, 53, 55-58, 60-75, 78-79, 84, 86, 88-89, 91-93, 95-96, and 98-100 were pending following Applicants' Amendment and Response filed on December 19, 2008.

In this paper, claims 1, 3, 4, 8, 10, 31-32, 37-39, 41-42, 44, 51, 67, 78-79, 84, 88-89, 91, 93, and 100 are amended, and claims 101-120 are newly added. With the entry of this amendment, claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41-44, 51, 53, 55-58, 60-75, 78-79, 84, 86, 88-89, 91-93, 95-96, and 98-120 are pending in this application.

Independent claims 1, 39, 42, 51, 93 and dependent claim 41 are amended to recite, and new claims 101-120 are added to recite, the presence of a first polyanion during the contacting step. Support for the use of such charged polymers is found at least in paragraphs [0056]-[0057] and [0194]-[0195] of the specification. The methods for contacting the first polyanion with the other reagents as recited in claims 1, 39, 41, 42, 51, 93, and 101-120 are also supported by at least paragraphs [0056]-[0057] and [0194]-[0195]. For clarity, claims 1, 3, 4, 8, 31, 32, 39, 42, 51, 78, 79, 84, 88, 89, and 91 are amended to specify that it is a second polyanion that is added to the separation media. Also for clarity, claim 93 is amended to specify that it is a second and a third polyanion that are employed in the concentrating and separating steps. Support for these amendments is found at least at paragraphs [0053]-[0057] and [0194]-[0195]. Claims 3, 4, 8, 78, 79, and 84 are also amended to include the independent selection of the polyanions, support for which is found at least at paragraphs [0053]-[0054].

Claims 1 and 93 are amended to recite that the polyanions reduce interference with separating the complex, and claims 39 and 42 recite reduced interference with the determination.

Support for these amendments are found at least in paragraphs [0017] and [0049]. Claim 51 is amended to recite that the polyanions reduce interference with concentrating the analyte.

Support for this amendment is found at least at paragraph [0192].

Claims 39 and 42 are amended to clarify that the labeled analyte and the charged carrier molecule-bound analyte recited in the claims, respectively, is distinct from the analyte in the sample. Although the analyte that is labeled or bound, respectively, is the same substance as the analyte to be detected in the sample, the substance that is labeled or bound, respectively, is obtained from an extrinsic source, and not from the sample. Claim 44 is amended to recite the names of the analytes in full. Support for these amendments are found at least in paragraph [0064], and the full names of these abbreviations were well known to those of skill in the art at the time of the application. The amendments to claims 10, 37, 38, 39, 41, 42, 67 and 100 are presented for clarity and consistency.

All of the above amendments either are supported by the specification and/or the original claims or are of a minor clerical nature. Accordingly, the amendments add no new matter. Applicants respectfully request reconsideration of the pending claims in the application.

I. Claim Rejections Under 35 U.S.C. § 112 - Indefiniteness

Claims 39, 41, 42 and 44 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse these rejections for the reasons that follow.

Claims 39, 41, and 42 were rejected as indefinite for allegedly lacking antecedent basis for the term “the analyte” as recited in step (i)(b) of the respective claims. Applicants respectfully traverse these rejections, particularly in view of the amendments presented in this paper to claims 39 and 42. Applicants have amended the claims to make clear that, although the

analyte recited in step (i)(b) is the same substance as the analyte of interest, it is not the analyte in the sample; rather it is from a source extrinsic to the sample. Claim 41, which depends from claim 39, also embodies this distinction.

Claims 39 and 41 were also rejected as indefinite for allegedly being unclear as to how the analyte in the sample is determined based on a measurement of only the labeled analyte. Applicants respectfully note that this type of method is referred to as a competitive assay format, and is well-known in the field of biological assays. A description of competitive assay formats is presented in the specification at least in paragraphs [0148]-[0158]. The competitive assay-based determination recited in these claims can be performed in accordance with this description, as well as with the knowledge of those of ordinary skill in the art.

Claim 44 was rejected as indefinite because it recites abbreviated forms of certain terms. Applicants have amended Claim 44, in the interest of clarity, to recite in full the names of terms previously abbreviated, with parenthetical reference to the abbreviation.

For the above reasons, Applicants respectfully request that the rejection of claims 39, 41, 42, and 44 under § 112, second paragraph be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 103 - Obviousness

A. Claims 1, 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, 91-92, and 95

Claims 1, 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, 91-92, and 95 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kawabata et al. (“Kawabata”), in view of Janssens et al. (“Janssens”). Applicants respectfully traverse these rejections for the reasons set forth below.

The analysis for obviousness must consider whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person of ordinary skill in the art. *See* 35 U.S.C. § 103. To reject a claim under 35 U.S.C. § 103(a), all the claim limitations must be taught or otherwise suggested by the prior art, and there must be some articulated reasoning with some rational underpinning to support the conclusion of obviousness. *See* MPEP § 2142.

The Office Action acknowledges that, with respect to claims 1 and 51, Kawabata does not teach a separation channel further filled with a polyanion, nor a concentration channel further filled with a polyanion. *See* Office Action at p. 5, 8, 10. The Office Action then states that Janssens teaches adding a polyanion to a capillary buffer in a capillary electrophoresis detection method, and alleges that it would be obvious to modify the method of Kawabata to include a separation channel which has a polyanion in a separation buffer as taught by Janssens. *Id.* at p. 11.

Without acquiescing to the allegation that Kawabata in view of Janssens renders certain claims obvious, the claims as amended include limitations that are not taught and not suggested by Kawabata and Janssens, alone or in combination. The claims are amended herein to further require, in step (i) of claims 1 and 51, contacting (a) the sample containing the analyte, (b) one or more affinity molecule/charged carrier molecule conjugates, and (c) a first polyanion. Step (ii) specifies that a “second polyanion” is added to the separation media. Moreover, although the first polyanion may be the same substance as the second polyanion recited in the claims, it is distinct from it in that the first polyanion is separately contacted with the sample, as mentioned above, and the second polyanion is expressly added to the separation media.

As stated in the Office Action, Kawabata does not teach a polyanion. *Id.* at p. 5. In the context of the amended claim, this indicates that Kawabata does not teach or suggest a second polyanion. Applicants do not acquiesce to any allegation in the Office Action that the teaching of Janssens renders the claimed use of the second polyanion obvious. Regardless, neither Kawabata nor Janssens teaches or suggests a polyanion of the first type. As noted by the Office, Kawabata does not teach a polyanion, and this applies to first polyanions as well. Janssens teaches the use of a polyanion (in conjunction with an initiator) for the treatment of a capillary, but does not teach contacting polyanions with the sample. Moreover, Janssens does not teach that a polyanion reduces the influence of sample interfering constituents as is claimed. Instead, Janssens teaches that when a polyanion is used in conjunction with an initiator (polycation or polyelectrolyte), the electroosmotic flow (EOF) is more stable in comparison to the “usual capillary electrophoresis method,” in which a capillary is not treated with the initiator/polyanion combination. Thus, neither reference teaches or suggests the limitation that a first polyanion is contacted with, among other things, the sample containing the analyte. The combination of references therefore cannot render the claims obvious because they do not teach or suggest all of the claim limitations.

If an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. As discussed above, neither Kawabata nor Janssens teaches or suggests all the limitations of independent claims 1 and 51, from which all other claims in this rejection depend. In particular, as discussed above, Kawabata and Janssens do not teach or suggest the use of a first polyanion present during complex formation of the analyte with an affinity molecule. Because the independent claims are nonobvious, dependent claims 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, and 95,

which depend from claim 1, and claims 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, and 91-92, which depend from claim 51, are also nonobvious.

For the reasons stated above, Applicants respectfully request that the rejection of claims 1, 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, 91-92, and 95, over Kawabata in view of Janssens under § 103 be withdrawn.

Applicants also acknowledge the Office's remark that Kawabata does not teach the limitations of claims 39, 42, and 93.

B. Claims 53 and 55-58

Claims 53 and 55-58 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kawabata in view of Janssens as applied to claims 1, 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, 91-92, and 95, further in view of Kaniansky et al. ("Kaniansky"). Applicants respectfully traverse these rejections for the reasons set forth below.

If an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. Claims 53 and 55-58 all depend from independent claim 51. As discussed above, Kawabata and Janssens do not teach or suggest all the claim limitations of independent claim 51, particularly contacting a first polyanion with the sample containing the analyte and with an affinity molecule conjugate. Kaniansky also does not teach or suggest this limitation.

The Office Action states that Kawabata and Janssens do not teach connecting a microchannel to a concentration channel, but that Kaniansky teaches such a device as well as an ITP concentration method. Office Action at p. 14-15. Applicants do not acquiesce to the allegation in the Office Action that it would be proper to combine Kaniansky with Kawabata and

Janssens to render the claims obvious. Regardless, Kaniansky does not teach contacting a polyanion with the sample and one or more conjugates. Kawabata, Janssens, and Kaniansky, alone or in combination, do not teach or suggest all the limitations of independent claim 51, from which claims 53 and 55-58 depend. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious. For these reasons, Applicants respectfully request that the rejection of claims 53 and 55-58 over Kawabata in view of Janssens, in further view of Kaniansky under § 103 be withdrawn.

C. Claim 66

Claim 66 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kawabata in view of Janssens as applied to claims 1, 3-4, 8-9, 11-14, 16-22, 27, 29, 31-32, 35, 37, 43-44, 51, 60-65, 68-70, 72-75, 78-79, 84, 86, 88-89, 91-92, and 95, further in view of Brown et al. (“Brown”). Applicants respectfully traverse these rejections for the reasons set forth below.

If an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. Claim 66 depends from independent claim 51. As discussed above, Kawabata and Janssens do not teach all the claim limitations of independent claim 51, particularly contacting a first polyanion with the sample containing the analyte and with an affinity molecule conjugate. Brown also does not teach or suggest this limitation.

Brown’s teaching is directed towards a modification of the claimed affinity molecule/charged carrier molecule conjugate. *See* Office Action at p. 16-17. As with Kawabata and Janssens, Brown also does not teach or suggest separately providing and contacting a polyanion with the sample and the conjugate.

Kawabata, Janssens, and Brown, alone or in combination, do not teach or suggest all the limitations of independent claim 51, from which claim 66 depends. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious. For these reasons, Applicants respectfully request that the rejection of claim 66 over Kawabata in view of Janssens, in further view of Brown under § 103 be withdrawn.

D. Claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92

Claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen et al. ("Chen"), in view of Janssens. Applicants respectfully traverse these rejections for the reasons set forth below.

The Office Action states that, with respect to claims 1, 39, and 51, Chen does not teach a separation channel further filled with a polyanion, nor a concentration channel further filled with a polyanion. *See* Office Action at p. 18, 22, 23, 24, and 25. The Office Action then states that Janssens teaches adding a polyanion to a capillary buffer in a capillary electrophoresis detection method, and alleges that it would be obvious to modify the method of Chen to include a separation channel which has a polyanion in a separation buffer as taught by Janssens. *Id.* at p. 27.

Without acquiescing to the allegation that Chen in view of Janssens renders certain claims obvious, Applicants assert that, as amended, the claims include limitations that are not taught and not suggested by Chen and Janssens, alone or in combination. As discussed above, the claims are amended herein to further require, in step (i) of claims 1, 39, and 51, contacting at least (a) the sample containing the analyte, (b) one or more affinity molecule/charged carrier

molecule conjugates, and (c) a first polyanion. Step (ii) specifies that a “second polyanion” is added to the separation media. Moreover, although the first polyanion may be the same substance as the second polyanion recited in the claims, it is distinct from it in that the first polyanion is separately contacted with the sample, as mentioned above, and the second polyanion is provided added to the separation media.

As stated in the Office Action, Chen does not teach a polyanion. *Id.* at p. 18, 22, 23, 24, 25. In the context of the amended claim, this indicates that Chen does not teach a second polyanion. Applicants do not acquiesce to any allegation in the Office Action that the teaching of Janssens renders the claimed use of the second polyanion obvious. Regardless, neither Chen nor Janssens teaches or suggests a polyanion of the first type. As noted by the Office, Chen does not teach a polyanion, and this applies to first polyanions as well. Janssens teaches the use of a polyanion (in conjunction with an initiator) for the treatment of a capillary, but does not teach contacting polyanions with the sample. Moreover, Janssens does not teach that a polyanion reduces the influence of sample interfering constituents. Instead, Janssens teaches that when a polyanion is used in conjunction with an initiator (polycation or polyelectrolyte), the electroosmotic flow (EOF) is more stable in comparison to the “usual capillary electrophoresis method,” in which a capillary is not treated with the initiator/polyanion combination. Thus, neither reference teaches or suggests the limitation that a first polyanion is contacted with, among other things, the sample containing the analyte. The combination of references therefore cannot render the claims obvious because they do not teach or suggest all of the claim limitations.

As set forth above, if an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. As discussed above,

neither Chen nor Janssens teaches or suggests all the limitations of independent claims 1, 39, and 51, from which all other claims in this rejection depend. In particular, as discussed above, Chen and Janssens do not teach or suggest the use of a first polyanion present during complex formation of the analyte with an affinity molecule. Because the independent claims are nonobvious, dependent claims 3-4, 8-14, 16-27, 29, 31-32, 35, 37-38, and 43-44, which depend from claim 1, claim 41, which depends from claim 39, and claims 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92, which depend from claim 51, are also nonobvious.

For the reasons stated above, Applicants respectfully request that the rejection of claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92 over Chen in view of Janssens under § 103 be withdrawn.

E. Claims 53 and 55-58

Claims 53 and 55-58 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Janssens as applied to claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92, further in view of Kaniansky.

Applicants respectfully traverse these rejections for the reasons set forth below.

As above, if an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. Claims 53 and 55-58 all depend from independent claim 51. As discussed above, Chen and Janssens do not teach all the claim limitations of independent claim 51, particularly contacting a first polyanion with the sample containing the analyte and with an affinity molecule conjugate. Kaniansky also does not teach or suggest this limitation.

The Office Action states that Chen and Janssens do not teach connecting a microchannel to a concentration channel, but that Kaniansky teaches such a device as well as an ITP

concentration method. Office Action at p. 28. Applicants do not acquiesce to the allegation in the Office Action that it would be proper to combine Kaniansky with Chen and Janssens to render the claims obvious. Regardless, Kaniansky does not teach or suggest contacting a polyanion with the sample and one or more conjugates. Chen, Janssens, and Kaniansky, alone or in combination, do not teach or suggest all the limitations of independent claim 51, from which claims 53 and 55-58 depend. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious. For these reasons, Applicants respectfully request that the rejection of claims 53 and 55-58 over Kawabata in view of Janssens, in further view of Kaniansky under § 103 be withdrawn.

F. Claim 66

Claim 66 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Janssens as applied to claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92, further in view of Brown. Applicants respectfully traverse these rejections for the reasons set forth below.

Again, if an independent claim is nonobvious under 35 U.S.C. § 103(a), then any claim depending therefrom is nonobvious. *See* MPEP § 2143.03. Claim 66 depends from independent claim 51. As discussed above, Chen and Janssens do not teach or suggest all the claim limitations of independent claim 51, particularly contacting a first polyanion with the sample containing the analyte and with an affinity molecule conjugate. Brown also does not teach or suggest this limitation.

Brown's teaching is directed towards a modification of the claimed affinity molecule/charged carrier molecule conjugate. *See* Office Action at p. 30-31. As with Chen and

Janssens, Brown also does not teach separately providing and contacting a polyanion with the sample and the conjugate.

Chen, Janssens, and Brown, alone or in combination, do not teach or suggest all the limitations of independent claim 51, from which claim 66 depends. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious. For these reasons, Applicants respectfully request that the rejection of claim 66 over Chen in view of Janssens, in further view of Brown under § 103 be withdrawn.

G. Claim 93

Claim 93 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Janssens and further in view of Kaniansky as applied to claims 53 and 55-58, further in view of Williams et al. (“Williams”). Applicants respectfully traverse these rejections for the reasons set forth below.

The Office Action states that, with respect to claim 93, Chen does not teach a separation buffer with polyanions, but alleges that Janssens’ teaching of adding a polyanion to a capillary buffer therefore teaches the claimed electrophoretic separation in a separation media with a [third] polyanion. *See* Office Action at p. 32-33. (Note that with the amendment submitted herein, what was previously recited as a “second polyanion” in claim 93 is now a “third polyanion.”) The Office Action further states that Kaniansky teaches “using a polyanion (methylhydroxyethylcellulose) in the buffer solution” for isotachopheresis, which renders obvious the claimed step of concentrated a complex in a concentration channel filled with a [second] polyanion. *See id.* at p. 33. (Note that with the amendment submitted herein, what was previously recited as a “first polyanion” in claim 93 is now a “second polyanion.”) Finally, the Office Action states that Chen, Janssens, and Kaniansky do not teach that the concentration

channel has at least one microscale dimension, but alleges that Williams provides such a teaching.

Even assuming, without acquiescing to any assertion that Janssens renders obvious the use of a third polyanion, none of the references teach or suggest a first polyanion. As described above, Chen, Janssens, and Brown do not teach or suggest separately providing and contacting a first polyanion with the sample and the conjugate. Williams also does not provide such a teaching or suggestion. Furthermore, Applicants respectfully indicate that Kaniansky does not teach or suggest a second polyanion. The methylhydroxyethylcellulose (MHEC) used by Kaniansky in the ITP buffer is not a polyanion. MHEC is a neutral molecule, wherein the functional groups, ethers and hydroxy groups, are not ionized at any relevant pH. Because the references lack any teaching of at least a first and a second polyanion, Chen, Janssens, Kaniansky, and Williams, alone or in combination, do not teach or suggest all the limitations of independent claim 93.

For the reasons stated above, Applicants respectfully request that the rejection of claim 93 over Chen in view of Janssens further in view of Kaniansky and further in view of Williams under § 103 be withdrawn.

H. Claims 95-96 and 98-99

Claims 95-96 and 98-99 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Janssens as applied to claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41, 43-44, 51, 60-65, 67-75, 78-79, 84, 86, 88-89, and 91-92, further in view of Kawabata. Applicants respectfully traverse these rejections for the reasons set forth below.

The Office Action alleges that Chen and Janssens teach the electrophoretic separation of “an analyte couple[d] to an affinity [molecule]/charged [carrier molecule] conjugate in a

separation buffer comprising a polyanion,” but that they do not teach the use of two more such conjugates. Office Action at p. 35. The Office Action then states that Kawabata supplies the teaching of an electrophoretic analytical method using two or more conjugates having an affinity for a target, and that these conjugates have an affinity for specific targets in the analyte. *Id.*

As already stated above, Chen, Janssens, and Kawabata do not teach or suggest contacting a first polyanion with at least the sample and affinity molecule/charged carrier molecule conjugates, a limitation introduced by the amendments presented in this paper. Thus Chen, Janssens, and Kawabata, alone or in combination, do not teach or suggest all the limitations of independent claim 1, from which claims 95 and 96 depend, and independent claim 39, from which claims 98 and 99 depend. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious.

For the reasons stated above, Applicants respectfully request that the rejection of claims 95-96 and 98-99 over Chen in view of Janssens and further in view of Kawabata under § 103 be withdrawn.

I. Claim 42

Claim 42 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hosokawa et al. (“Hosokawa”) in view of Janssens. Applicants respectfully traverse these rejections for the reasons set forth below.

The Office Action states that Hosokawa teaches the formation of a first complex and a second complex in accordance with the claimed method, but does not teach providing a separation channel filled with a separation media and a polyanion. Office Action at p. 37-38. The Office Action then states that Janssens teaches adding a polyanion to a capillary buffer in a capillary electrophoresis detection method, and alleges that it would be obvious to modify the

method of Hosokawa to include a separation channel which has a polyanion in a separation buffer as taught by Janssens. *Id.* at p. 38.

Applicants respectfully assert that Hosokawa at least does not teach a first complex consistent with the elements of claim 42. Claim 42 recites a first complex comprising, e.g., (i) a charged carrier molecule-bound analyte, wherein the analyte is from a source extrinsic to the sample, and (ii) a labeled affinity molecule. Claim 42 also recites a second complex, which comprises (i) analyte present in the sample and (ii) a labeled affinity molecule, and which forms in competition with the first complex. That is, two species of analyte compete to form a complex with a labeled affinity molecule: (a) analyte that is present in a sample, and (b) analyte bound to a charged carrier molecule, which is prepared from analyte not from the sample. In contrast, Hosokawa only teaches methods using analyte in the sample. *See, e.g.*, Hosokawa at p. 5-9. The methods of Hosokawa are limited to assaying an analyte in a sample without the introduction of any extrinsic, modified analyte to the assay.

Without acquiescing to the allegation that Janssens may be properly combined with Hosokawa, Applicants assert that, as amended, the claims include limitations that are not taught and not suggested by Hosokawa and Janssens, alone or in combination. The claims are amended herein to further require, in step (i) of claim 42, contacting at least the sample containing the analyte, an affinity molecule labeled by a detectable marker, and a first polyanion. Step (ii) specifies that a “second polyanion” is added to the separation media. Moreover, although the first polyanion may be the same substance as the second polyanion recited in the claims, it is distinct from it in that the first polyanion is separately contacted with the sample, as mentioned above, and the second polyanion is provided added to the separation media.

As stated in the Office Action, Hosokawa does not teach a polyanion. *Id.* at p. 38. In the context of the amended claim, this indicates that Hosokawa does not teach a second polyanion. Applicants do not acquiesce to any allegation in the Office Action that the teaching of Janssens renders the claimed use of the second polyanion obvious. Regardless, neither Hosokawa nor Janssens teaches or suggests a polyanion of the first type. As noted by the Office, Hosokawa does not teach a polyanion, and this applies to first polyanions as well. Janssens teaches the use of a polyanion (in conjunction with an initiator) for the treatment of a capillary, but does not teach contacting polyanions with the sample. Moreover, Janssens does not teach that a polyanion reduces the influence of sample interfering constituents. Instead, Janssens teaches that when a polyanion is used in conjunction with an initiator (polycation or polyelectrolyte), the electroosmotic flow (EOF) is more stable in comparison to the “usual capillary electrophoresis method,” in which a capillary is not treated with the initiator/polyanion combination. Thus, neither reference teaches or suggests the limitation that a first polyanion is contacted with, among other things, the sample containing the analyte. The combination of references therefore cannot render the claims obvious because they do not teach or suggest all of the claim limitations.

For the reasons stated above, Applicants respectfully request that the rejection of claim 42 over Hosokawa in view of Janssens under § 103 be withdrawn.

J. Claim 100

Claim 100 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hosokawa et al. (“Hosokawa”) in view of Janssens as applied to claim 42, and further in view of Kawabata. Applicants respectfully traverse these rejections for the reasons set forth below.

The Office Action alleges that Hosokawa and Janssens teach the electrophoretic separation of “two complexes of analyte based upon the sizes and mobility of analyte/labeled affinity and charged carrier/analyte/labeled affinity,” but that they do not teach the use of two more such conjugates. Office Action at p. 39. The Office Action then states that Kawabata supplies the teaching of an electrophoretic analytical method comprising forming two or more affinity molecules, and that these affinity molecules bind to specific targets in the analyte. *Id.*

As already stated above, Hosokawa, Janssens, and Kawabata do not teach or suggest contacting a first polyanion with at least the sample and affinity molecule/charged carrier molecule conjugates, a limitation introduced by the amendments presented in this paper. Thus Hosokawa, Janssens, and Kawabata, alone or in combination, do not teach or suggest all the limitations of independent claim 42, from which claim 100 depends. Therefore these references, considered as a whole, do not render the claims, considered as a whole, obvious.

For the reasons stated above, Applicants respectfully request that the rejection of claim 100 over Hosokawa in view of Janssens and further in view of Kawabata under § 103 be withdrawn.

III. Conclusion


In view of the foregoing amendments and remarks, Applicants respectfully request entry by the Examiner of this Amendment under 37 C.F.R. § 1.111, reconsideration of this application, and the timely allowance of claims 1, 3-4, 8-14, 16-27, 29, 31-32, 35, 37-39, 41-44, 51, 53, 55-58, 60-75, 78-79, 84, 86, 88-89, 91-93, 95-96, and 98-120. Applicants submit that the proposed amendments to the claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships

were either claimed earlier or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Respectfully submitted,

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